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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/991,143	12/16/97	CONTI-FINE	B 600.423US1

HM12/1204

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EXAMINER	
NOLAN, P	
ART UNIT	**PAPER NUMBER**
1644	24

DATE MAILED: 12/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/991,143	Corti-Fine
Examiner	**Group Art Unit**
Nolan	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 9-5-00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 1-13, 16-18, 31 and 34-39 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1-13, 16-18, 31 and 34-39 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 23

☒ Notice of References Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other_____

Office Acti n Summary

Part III DETAILED ACTION

1. This application is a continuation-in-part of 08/564,972.

2. Claims 1-13, 16-18, 31 and 34-39 are pending.

3. The request filed on 9-5-00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/991,143 is acceptable and a CPA has been established. An action on the CPA follows.

4. Claims 1-13, 16-18, 31 and 34-39 may not have the benefit under **35 USC § 120** of the parent filing date (11-30-95), because the claimed methods are not disclosed in the parent applications, serial numbers 08/564,972.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-13, 16-18, 31 and 34-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating EAMG mice with ACHR peptides, does not reasonably provide enablement for treating humans with endogenous or exogenous universal antigens nasally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Applicant's specification is limited to one in vivo working example in mice demonstrating the enablement of the claimed invention. However, as readily recognized by Applicant in their response of 9-5-00 page 10, first paragraph, one of skill in the peptide therapy art would not reasonably expect effective animal therapy data to translate to human therapy effectiveness. In addition the only prior art example of exogenous human therapy with a universal immunodominant epitope, Norman et al., teaches effective cat allergy therapy with T cell reactive peptides did not result in decreased antibody production or T cell reactivity. Since Applicant's claimed invention requires the peptide therapy to result in reduced undesirable antibody production and decreased CD4+ T cell activity and the prior art example using a T cell universal epitope in exogenous peptide therapy of humans did not result in decreased antibody production or T cell reactivity but

did result in treatment it would be unpredictable to practice the full scope of Applicant's claimed invention.

In regards to endogenous peptide therapy, the goal of peptide immunotherapy of T-cell-mediated autoimmunity is to induce anergy in self reactive T cells. However Wraith et al., (U, Cell 59: 247-255, 1989) teach the "Inhibition of the response restricted by one class II molecule may lead only to the escape to an autoimmune response to a separate epitope restricted by a different class II molecule." (page 253 column 1, in particular). Applicant has provided only limited murine in vivo experiments to demonstrate operability of the endogenous peptides. Since human and mice display different MHC haplotypes and applicant has given no guidance as to how their peptide specific therapy would overcome autoreactive T cell escape mechanisms in humans it would require and undue amount of experimentation to one of skill in the art to practice the claimed invention and this is not sanctioned by the statute.

Furthermore, Tisch et al., (V, P.N.A.S. 91:437-438) teach that treating an ongoing T-cell-mediated autoimmunity by administering an antigen peptide may have an immunizing effect and exacerbate the disease condition (page 437, column 3, in particular). Since applicant has not provided any working examples of the efficacy of the endogenous peptides in treating already established autoimmune diseased patients, it would require and undue amount of experimentation to one of skill in the art to practice the claimed invention and this is not sanctioned by the statute.

Lastly, Applicant has not enabled the recitation of the term "variant". The breadth of Applicant's claims would encompass limitless amounts of possible peptides because of the term variant. Applicant has demonstrated that one peptides out of this entire genus can meet the limitations of their claims. Does Applicant contend that a showing of one peptide would read on this entire genus? The state of the art as taught by Karin et al., demonstrates that a substitution of an phenylalanine with alanine (i.e. a conservative amino acid substitution) at position 89 resulted in an increase in T cell proliferation, binding affinity of the peptide and induction of EAE in rats, while the same amino acid substitution, an phenylalanine for an alanine, at position 90, resulted in the exact opposite results, decreased binding, T cell proliferation and no induction of EAE (see Table 1, in particular). What the results of the Karin et al., article indicate is that the effects of amino acid changes on peptide-MHC binding, T cell proliferation and in vivo effects of said peptides is unpredictable. Since Applicant has provided little guidance in their specification as to how one of skill in the art would overcome such unpredictability of the effects amino acid changes have on the peptides, it would require an undue of experimentation to practice Applicant's claimed invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 to 4:30.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
December 2, 2000